UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

In Re: COOK MEDICAL, INC., IVC FILTERS MARKETING, SALES PRACTICES AND PRODUCT LIABILITY LITIGATION	)	1:14-ml-02570-RLY-TAB MDL No. 2570
This Document Relates to:	)	
Tonya Brand, 1:14-cv-06018-RLY-TAB	)	

ENTRY ON THE PLAINTIFF'S MOTION TO EXCLUDE OR LIMIT THE TESTIMONY OF RENU VIRMANI, M.D.

Plaintiff challenges three opinions advanced by Cook's retained expert, Dr. Renu Virmani. They are: (1) filters "function to trap clots"; (2) "[s]mall clots are not concerning," while large clots "more likely are being caught in the filter on their way from the pelvic and leg veins"; and (3) "the Celect and Tulip[] are not inherently thrombogenic." (Filing No. 8639-6, Expert Report of Dr. Virmani ("Expert Report") at 31-32). Plaintiff argues her opinions must be excluded because she lacks the qualifications to offer them and the opinions are unreliable and irrelevant. For the reasons set forth below, the court **DENIES** Plaintiff's motion.

I. Standard for Expert Testimony

Federal Rule of Evidence 702 and the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) establish the framework for

analyzing the admissibility of expert testimony. *Naeem v. McKesson Drug Co.*, 444 F.3d 593, 607 (7th Cir. 2006). To be admissible, expert testimony must satisfy four requirements under Rule 702: (1) the expert must be qualified by knowledge, skill, experience, training, or education; (2) the proposed expert testimony must assist the trier of fact in determining a relevant fact at issue in the case; (3) the expert's testimony must be based on sufficient facts or data and reliable principles and methods; and (4) the expert must have reliably applied the principles and methods to the facts of the case. *Lees v. Carthage College*, 714 F.3d 516, 521-22 (7th Cir. 2013) (citations omitted). As the proponent of the expert testimony at issue, the Cook Defendants have the burden of demonstrating the expert's admissibility. *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009).

II. Discussion

A. Qualifications

Dr. Virmani is a cardiovascular pathologist. She currently serves as the President of CVPath Institute, a non-profit organization that "provides consultation, histology, and diagnostic services to promote discoveries that advance the diagnosis, treatment, and management of cardiovascular diseases." (Expert Report at 1). The organization "possesses one of the largest and most comprehensive repositories of diseased human tissue that is available for investigative studies and teaching." (*Id.*).

During her career, she has performed pre-clinical animal studies on cardiovascular implantable devices which were later approved by the FDA, including pre-clinical studies on IVC filters (Boston Scientific's Greenfield Vena Cava Filter, Novate Medical's Sentry

IVC Filter, and the Cordis OPTEASE Filter). (*Id.* at 1-2). She has also observed and evaluated tissues from patients who had IVC filters in place. (*Id.* at 2).

Dr. Virmani has authored over 700 publications in peer-reviewed journals and delivered more than 800 presentations globally. (*Id.* at 1). In addition, she is familiar with clotting as it relates to vascular devices and has given lectures on coagulation. (Filing No. 8639-2, Deposition of Dr. Virmani at 64). And through her study, she has "seen filters with clots on them" and has witnessed "clots organize over time and [] shrink in size." (*Id.* at 201).

Plaintiff argues Dr. Virmani is not qualified because she is not an expert in clot-trapping or a hematologist. But "Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience." *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) (citing *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 591 (7th Cir. 2000)). Dr. Virmani certainly has the background and experience to testify about the function of medical devices in the vascular system, how animal studies support that intended function, and whether medical devices are thrombogenic. The court therefore finds she is qualified to offer the challenged opinions in this case.

B. Reliability

In forming her opinion on the thrombogenicity of Cook's filters, Dr. Virmani reviewed the animal study slides from Cook's animal studies and "didn't see any clot formation that occurred [in Cook's long-term animal studies], even after 180 days, and beyond 365 days. So, if [the filters] were still thrombogenic, we should have seen some." (Virmani Dep. at 204). At her deposition, Plaintiff pressed Dr. Virmani for a more

specific methodology other than the absence of clots in Cook's animal studies. Dr. Virmani explained "it is impossible[1] to determine [] whether a filter is causing a clot or it's trapping the clot. Unless and until you could visualize everything throughout the patient's life, I don't think you can make that decision." (*Id*. at 206). Plaintiff points to this testimony and argues Dr. Virmani's opinions are speculative and should be excluded.

Dr. Virmani's opinion is not speculative; it is based on her experience and knowledge gleaned from the animal studies she has developed and performed over the course of her career, the published literature on IVC filters in animals, and Cook's Data Summary. (Expert Report at 32). This is an accepted methodology for a pathologist. *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 570070, at *4 (S.D. W. Va. Feb. 11, 2015) (holding a pathologist's testimony was reliable where he "reviewed pathological slides, compared his observations to published medical literature, and provided diagnostic interpretations of what he saw"); *see also Eve v. Santoz Pharm. Corp.*, IP 98-1429-C-Y/S, 2001 U.S. Dist. LEXIS 4531, *72-74 (S.D. Ind. March 7, 2001) (finding animal study evidence to be "scientifically reliable" under *Daubert* because there were "good grounds" to extrapolate from animals to humans, such as published studies in peer-reviewed journals). Any weaknesses in her opinion may be addressed on cross-examination.

[1] Cook's other expert, Dr. David Gillespie, held a similar view. (Filing No. 8615-2, Deposition of Dr. Gillespie at 235 (testifying he could not point to any image from Plaintiff's medical records demonstrating that her filter caught a clot because it would require him to "continuously image [Plaintiff]" which would be "medically unethical")).

Next, Plaintiff faults Dr. Virmani for citing no authority for her opinion that "small clots are not concerning" while large clots "more likely are being caught in the filter on their way from the pelvic and leg veins." At her deposition, Dr. Virmani explained:

> When you do autopsies, you often see patients who are dying of pulmonary emboli. They're usually large clots. And those that get small clots, they go to smaller branches and usually don't result in infarcts or sudden death or anything.

(*Id.* at 207). Thus, the basis of her opinion is her extensive experience as a cardiovascular pathologist. As such, her opinion is admissible. *Smith*, 215 F.3d at 718.

And lastly, Plaintiff attacks Dr. Virmani's opinion that the Celect functions to capture clots. She explained that the Celect is designed to capture clots; if a clot "flows in the central [sic], it is going to gather." (Virmani Dep. at 202). She also reviewed the medical literature and the PREPIC I study, which showed that, for a 30-day period, patients without a filter had a larger number of pulmonary emboli as compared to those with a filter. (*Id.*). Reviewing published literature and the results of clinical studies is a reliable methodology. As such, her opinion is admissible.

III. Conclusion

Dr. Virmani has the expertise to opine on the clot-trapping ability and thrombogenicity of the Celect. Therefore, Plaintiff's Motion to Exclude or Limit the Expert Testimony of Renu Virmani, M.D. (Filing No. 8636) is **DENIED**.

SO ORDERED this 12th day of December 2018.

RICHARD L. YOUNG, JUDGE
United States District Court
Southern District of Indiana

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